REMARKS

In response to the non final Office Action mailed 8 January 2003, the present application has been carefully reviewed and amended. Entry of the present amendment and reconsideration of the application is respectfully requested.

Rejection Under 35 U.S.C. §102

Claim 43 stands rejected under 35 U.S.C. §102(e) as being anticipated by Quinn et. al. (US 6,036,654).

Independent Claim 43 has been amended to recite in part "an inflatable stenosis reducing balloon".

Quinn discloses a flotation balloon 32. A floatation (location) balloon is not a stenosis reducing balloon. As set forth in the present application on page 9, lines 13-25 and page 10, lines 1-23:

> It is understood that locating balloons are used with catheters. These locating balloons are fundamentally different than angioplasty balloons. The locating balloon is an elastic member. Locating balloons are generally spherical and are capable of withstanding just sufficient pressure to partially inflate in the blood flow. Inflation pressures are relatively low, on the order of one psi. *The elastic construction of the locating balloon is such that the balloon may be subject to increased inflation pressure and increased diameter up to failure. The geometry of the locating balloon is selected to allow the balloon (and accompanying catheter) to be carried along a vessel by the blood flow. That is, the geometry of the locating balloon sufficiently increases the hydrodynamic resistance to blood flow to translate the balloon and catheter along the vessel.*
>
> In contrast, an angioplasty balloon is a generally elongate inelastic inflatable member capable of relatively high pressures. *The angioplasty balloon is only expandable to a predetermined size or cross sectional area. Compared to the locating balloon, angioplasty balloons may require inflation pressures greater than 2 psi and as high as 20 psi or greater. The elongate structure of the angioplasty balloon provides for relatively complete contact along the narrowing of the vessel. That is, the spherical locating balloon presents only a point or ring of contact with the surrounding vessel. The angioplasty balloon contacts a length of the vessel to provide relatively constant pressure along the length of contact. In addition, a slight inflation of the locating balloon is used to increase a resistance to blood flow which in turn causes translation of the balloon*

along the vessel, thereby allowing the locating balloon to the disposed along a vessel. In contrast, a slight inflation of the angioplasty balloon permits flow around and along the balloon and does not create sufficient resistance to flow to induce translation of the balloon (and catheter) along the vessel. Use of a locating balloon to perform angioplasty would allow an elastic balloon to be inflated within the vessel such inflation of an elastic member could rupture the vessel. Alternatively, the elastic member of the locating balloon may not have sufficient strength to displace the vessel wall and perform the angioplasty. [emphasis added] (Page 9, lines 13-25 and Page 10, lines 1-23 of the present application)

Applicant is unable to find any suggestion in Quinn that the Quinn [locating] balloon is used "in vascular corrective procedures."

Further, Examiner Szmal has previously recognized that Quinn fails to disclose;

(a) The use of a catheter having a stenosis reducing member in order to perform a vascular corrective procedure. [Paper 9, page 3]

In addition, Quinn expressly and repeatedly recites the balloon as a floatation (locating) balloon. "a balloon inflation lumen for catheter floatation" [Col. 1, Lines 56-57]; "no one has designed a flotation balloon catheter . . ." [Col. 1, Lines 36-37], "the distal end of the catheter 12 includes a balloon 32 at the distal tip for flotation of catheter . . . " [Col. 4, Lines 25-26]

Therefore, as Claim 43 recites "an inflatable stenosis reducing balloon" which is not present in Quinn, and such absence has been expressly recognized by the Examiner, Claim 43 is in condition for allowance.

Rejections Under 35 U.S.C. §103

Claims 2-6, 9-19 and 22-42 stand rejected under 35 U.S.C. §103 as being unpatentable over Quinn et. al. (US 6,036,654) in view of Vogel, et al., (US 4,957,110). [Paper 23, Page 3]

Quinn

Examiner Szmal relies upon Quinn, *et al.* to disclose a multi-lumen, multi-parameter catheter and its method of use that has:

1. The use of a catheter body having a balloon[1];
2. a port in the catheter body for inducing a blood property change to flowing blood external to the catheter;

3. a sensor affixed to the catheter and spaced away from the blood property change port to provide a signal corresponding to a change in blood property external to the catheter;
4. the sensor is located in the catheter to minimize wall effects;
5. a controller connected to the sensor to calculate the flow rate corresponding to the signal from the downstream sensor;
6. the port includes an aperture for introducing a blood property variant;
7. the blood property change port in the sensor are spaced apart by sufficient distance to substantially mix an indicator into the blood;
8. the port includes at least one of a heat sink and the heat source for creating a local temperature gradient;
9. a dilution indicator port;
10. the change in blood property includes one of a bolus injection and a constant infusion;
11. the blood altering section includes one of a port and a temperature gradient generator;
12. the sensor detects changes in one of electrical impedance and electrical resistance; and
13. the sensor detects the thermal property of the blood. Citing Column 3, lines 25 -- 63; Column 4, lines and 60 -- and 67; Column 5 lines 1 -- 7 and 26 -- 29; and Column 6, lines 33 -- 44. [Paper 23, page 3]

Examiner Szmal states that Quinn fails to disclose;

1. The use of a specific formula for the controller or processor to calculate the flow rate after the bolus is injected;

2. The use of multiple catheters; and

3. The stenosis reducing procedure includes angioplasty.

Applicant respectfully disagrees with the Examiner's construction and interpretation of Quinn.

Specifically, Examiner Szmal has previously recognized that Quinn fails to disclose;

(a) The use of a catheter having a stenosis reducing member in order to perform a vascular corrective procedure; [Paper 9, page 3]

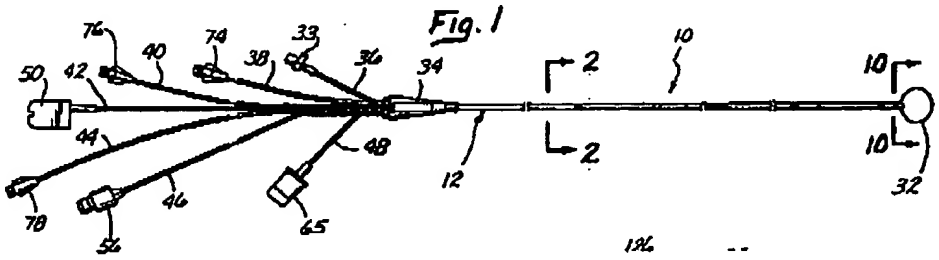
[1] Applicant notes this is a locating balloon, not a stenosis reducing member.

(b) Inserting the catheter to the site of the stenosis; [Paper 9, page 3]

(c) Reducing the stenosis in the vessel [Paper 9, page 3]; and

(d) Performing angioplasty to reduce the stenosis in the vessel. [Paper 9, Page 3]

Quinn is expressly directed to a flotation balloon catheter selected to continuously measure cardiac output and measured mixed venous oxygen saturation. (Col. 1, lines 36-40).



(Col. 1, lines 37-38; Col. 1, lines 56-57; Col. 4, lines 26-32) That is, the Quinn balloon 32 is a locating balloon, not a stenosis reducing balloon. As previously set forth, and reasserted in this analysis, a floating (locating) balloon is not an angioplasty (stenosis reducing) balloon.

Quinn + Vogel

Since both Quinn and Vogel disclose means for measuring the flow rate within a blood vessel by a dilution technique the Examiner asserts it would have been obvious to modify Quinn to:

1. Include the use of a specific blood flow formula;

2. Use multiple catheters; and

3. Reducing the stenosis using the balloon.

The Examiner also asserts it would have been obvious "to use the balloon of Quinn et al. for an angioplasty procedure, since any balloon on the end of a catheter would be capable of inflation to reduce the stenosed region." [Paper 23, page 4]

The Examiner further asserts it would have been obvious "to have the processor of Quinn et al. to use the formula disclosed in Vogel et al. to calculate the post bolus injection flow rate, since it is well known and a part to use that formula to determine the blood flow in regular dilution or thermodilution techniques." [Paper 23, page 4]

The Examiner further asserts it would have been obvious "to conduct a pre - and post angioplasty flow rate and perform the procedure again if the flow rate is not sufficient." [Paper 23, page 4] [2]

The Examiner also asserts it would have been obvious "to rotate the sensor to reduce the wall effects in the vessel since it is well known and a part catheters have the ability to be rotated while in the blood vessel." [Paper 23, page 4 - page 5]

The Examiner finally asserts it would have been obvious "to provide multiple sensors on the catheter since it would provide a way to monitor a wide range of blood parameters, including oxygenation, glucose levels, flow rate and cholesterol levels." [Paper 23, page 5]

Claims 2-6, 30, 31, 34 and 36

Claims 2 through 6, 30, 31 and 36 depend from independent Claim 34.

Claim 34 recites in part "an elongate catheter having *a stenosis reducing member, a* blood property change port located to alter a blood property outside the catheter and *a downstream sensor affixed to the catheter and spaced from the port* for producing a signal corresponding to a blood property in a blood flow in the vessel." [emphasis added]

The primary reference Quinn has previously been recognized by the Examiner as failing "to disclose;

(a) The use of a catheter having a stenosis reducing member in order to perform a vascular corrective procedure; [Paper 9, page 3]

(b) Inserting the catheter to the site of the stenosis; [Paper 9, page 3]

(c) Reducing the stenosis in the vessel [Paper 9, page 3]; and

(d) Performing angioplasty to reduce the stenosis in the vessel [Paper 9, Page 3]"

Vogel

Vogel cannot cure the deficiencies of Quinn. Vogel is directed to a steerable guide wire, which is used in conjunction with a *separate* dilatation catheter.

The inventive aspect of Vogel is a guidewire having electrodes for measuring blood flow and vessel cross section. The guidewire of Vogel does not include a stenosis reducing member nor a port for introducing a blood property change. Rather, Vogel merely discloses a proximal

[2] Applicant submits there is no support in either reference for this modification, and that absent the present

electrode 22 and a distal electrode 20 along a guidewire 10. Specifically, Vogel is directed to a small diameter, steerable guidewire that is provided with a pair of electrodes for measuring vessel cross-section and coronary blood flow. (Col. 1, Lines 10-12)

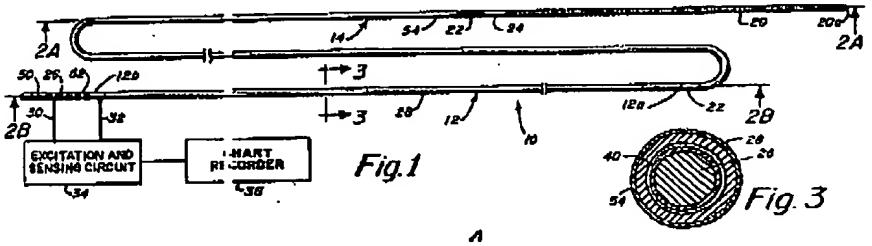


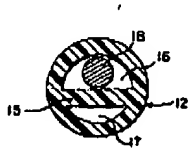
Fig.1

Fig. 3

Examiner Szmal asserts Vogel discloses each of the limitations of the present claims, citing Col. 8, Lines 24-66 and Col. 9, Lines 5-47.

Vogel does not disclose a dilatation catheter having a blood property sensor. The Vogel guidewire is recited as being used in conjunction with a dilatation catheter of U.S. Patent No. 4,545,390. The Vogel guidewire is slideably received within a lumen of the dilatation catheter. That is, the Vogel guidewire can be used in cooperation with a dilatation catheter, wherein the dilatation catheter is described in U.S. Patent No. 4,545,390. (Col. 8, Lines 24-30) A cross section of the dilatation catheter in U.S. Patent No. 4,545,390 is:

Fig.3



where reference 12 is the dilatation catheter of the '390 patent and reference 18 is the Vogel guidewire.

The dilatation catheter 12 of the '390 patent includes the stenosis reducing member and main lumen 16, and is used in combination with the separate and independent Vogel guidewire, wherein the Vogel guidewire includes the electrodes for measuring a blood parameter. The

disclosure, such combination would not even be imagined from the references.

Vogel guidewire does not include a stenosis reducing member and the dilatation catheter does not include a sensor.

Vogel states the guidewire 10 axially extends and travels through the main lumen of a separate and independent dilatation catheter. That is, the guidewire is axially (longitudinally) translatable relative to the dilatation catheter.

Specifically, Vogel states,

> As the stenosis or obstruction is approached, the guidewire is advanced independently of the dilatation catheter in order to locate the guidewire with a high degree of precision with respect to the stenosis.

Vogel expressly requires and employs the sensors of the guidewire to *move relative to and independently of the dilatation catheter and thus the stenosis reducing member.*

In fact, the Vogel continues,

> The guidewire is advanced to the stenosed region by a combination of pushing and rotation or steering of its proximal end.

After a measurement of the vessel has been taken, the dilatation catheter is then again moved relative to the guidewire. Specifically,

> Then, the dilatation catheter is advanced over the guidewire until the balloon is located within the obstruction.

Further, Vogel actually translates the dilatation (balloon) catheter relative to the electrodes after the dilatation procedures.

> After the dilatation procedure has been completed, the balloon catheter is withdrawn, at least partially, and the electrodes 20 and 22 are again positioned in the stenosed region..

Therefore, Vogel requires relative movement between the electrodes of the guidewire and the dilatation catheter.

Thus, the primary reference does not disclose the catheter having a stenosis reducing member and a secondary reference merely discloses a steerable guide wire for measuring blood flow, wherein the guide wire can be used with a separate dilatation catheter. There is no disclosure neither reference for the proposed combination by the Examiner. Applicant respectfully submits absent applicant's disclosure, the references would not be combined.

The proposed combination of Quinn and Vogel would most accurately result in use of the steerable guide wire of Vogel in connection with the inflation balloon of Quinn.

The Examiner further asserts "it would also have been obvious to an ordinary skill and are to use the balloon of Quinn et al. for angioplasty procedure, since any balloon on the end of the catheter would be capable of inflation to reduce the stenosed region." [Paper 23, page 4]

The Examiner has provided no basis for this alleged obviousness. That is, the present application expressly set forth the distinctions between a locating balloon (as in Quinn) and a stenosis reducing balloon. The Examiner has not identified any portion of either reference which would sustain or even suggest the proposed interchangeability of a floatation balloon and a stenosis reducing balloon.

The outstanding rejection relies upon the proposed interchangeability of a locating balloon and a stenosis reducing member. However, the distinction between locating balloons and stenosis reducing balloons is set forth on page 9, lines 13-25 and page 10, lines 1-23 of the present application. There is no basis in either of the references to suggest interchanging a locating balloon and a stenosis reducing member.

Applicant is unable to find any suggestion in Quinn that the Quinn [locating] device is used "in vascular corrective procedures."

"Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [citations omitted] *In re Kotzab*, 217 F 3d 1365, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000)

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. [citations omitted] *Id.* at 1317.

The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. Broad conclusory statements standing alone are not "evidence." [citations omitted] *Id.* at 1317.

There are no particular findings supporting the position of Examiner Szmal. Applicant respectfully submits the repeated assertion that "It would also have been obvious.." is insufficient.

While the test for establishing an implicit teaching, motivation or suggestion is what the combination of these two statements of Evans would have suggested to those of ordinary skill in the art, . . . particular findings must be made as the reason the skilled artisan, with no knowledge of the claimed invention would have selected these components for combination in the manner claimed. Kotzab [Absent a specific understanding or principal within the knowledge of the skilled artisan that would have motivated, with no knowledge of the present invention, to make the combination in the claims.]

"Our case law makes clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." [citations omitted] *Ecolochem v. Southern California Edison Co.* 56 USPQ2d 1065, 1073 (Fed. Cir. 2000).

"Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Id.* "The opinion then lists each step and states where in the cited prior art references the step can be found. This reference-by-reference, limitation-by-limitation analysis wholly fails to demonstrate how the prior art teaches or suggests the combination claimed in the '411 patent." *Ecolochem*

The Federal Circuit has stated the implicit generalized finding by a district court that when one of ordinary skill was faced with a problem [of the patent] in view of a prior art reference, that the combination claimed would have been obvious is insufficient. *Ecolochem*

"A rejection cannot be predicated on the mere identification of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention would have selected these components for combination in the manner claimed." *Ecolochem*

The outstanding rejection is contrary to a number of the requirements for an obviousness rejection. Specifically:

1. The problem Examiner Szmal alleges to be solved is defined in terms of its solution. That is, the Examiner asserts "Since both Quinn et al. and Vogel et al. disclose means for measuring the flow rate within a blood vessel by a dilution technique, it would have been obvious to include the recited formula, and use a stenosis reducing balloon (contrary to Quinn) [Paper 23, page 4] This reveals improper hindsight in the selection of the prior art relevant to obviousness.

Further, while Examiner Szmal relies upon the "obviousness" to use a single catheter [Paper 9, page 3], the Examiner states "It would also have been obvious to have separate catheters to perform the corrective procedure and determine the blood flow since it would allow the surgeon to remove the blood flow sensor when the corrective procedure is underway and would also allow for the insertion of the sensor to the stenosis site once the procedure is completed in order to determine the second blood flow rate." [Paper 9, Page 4] The references are now construed to such that it would be obvious to . . . for "the use of multiple catheters and

reducing a stenosis using the balloon . . . since it would provide a means to measure the pre and post angioplasty flow rates . . " [Paper 23, Page 4] Applicant respectfully submits the references, with the same suggestions to one of ordinary skill in the art, cannot suggest both a single catheter and not a single catheter.

2. Examiner Szmal has not made any showing of a teaching or motivation to combine the prior art references. The Examiner states "It would also have been obvious to..". However, the justification for the asserted obvious combination is to achieve the claimed invention – and not what the cited references suggest.

3. The Office Action [Paper 23] does not provide a specific understanding or principal within the knowledge of the skilled artisan that would have motivated, *with no knowledge of the present invention*, to make the combination in the claims. That is, each asserted obvious combination by Examiner Szmal is solely in terms of the present invention, rather than any basis in the cited references for substituting locating balloons and stenosis reducing member.

Not only is there no suggestion to modify Quinn, but to modify Quinn to employ a stenosis reducing member would be expressly contrary to Quinn. That is, the examiner requires one to ignore the reasonable skill in the art and indiscriminately interchange whatever pieces and parts are located in the prior art. That is, the purported interchangeability or modification of flotation balloon for a stenosis reducing balloon is not obvious to one of ordinary skill in the art. There is no suggestion in Quinn of stenosis reducing members.

Therefore, the rejection of Claim 34 under 35 U.S.C. §103 cannot be sustained. As Claims 2-6, 30 and 31 and 36 depend from Claim 34, and include all limitations thereof, these claims are also in condition for allowance.

Claim 9

Independent Claim 9 recites in part,

"(a) a catheter body having a stenosis reducing member selectively actuatable to reduce stenosis in a vessel;

(b) a port in the catheter body for inducing a blood property change to blood flowing external to the stenosis reducing catheter, *the blood property change port located a fixed distance from the stenosis reducing member*; and

(c) a sensor affixed to the catheter body and *spaced a given distance from the blood property change port* for providing a signal corresponding to a change in a blood property external to the stenosis reducing catheter...." [emphasis added]

Quinn fails to disclose a stenosis reducing member selectively actuatable to reduce stenosis in a vessel. Vogel cannot cure the deficiencies as Vogel employs a steerable guide wire which is movable relative to a dilatation catheter. As set forth in the prior discussion of Vogel, the catheter body employed in Vogel does not include a sensor, but rather the steerable guidewire that is disposed for axial translation within and along the catheter includes the sensors. Therefore, Vogel does not disclose a sensor affixed to a catheter body, wherein the catheter body has a stenosis reducing member. The relative motion between the port, the sensor and the stenosis reducing member are expressly contrary to Vogel.

Absent applicant's disclosure, Examiner Szmal has not provided any basis for ignoring the relative movable inseparable components of Vogel. Further, no basis, outside of the present claims, has been provided for equating or substituting inflation balloons and stenosis reducing members. Again, there is no basis for interrupting flow in a device for continuous monitoring.

As the asserted combination further fails to satisfy the statutory requirements of §103, applicant respectfully submits the rejection of Claim 9 under 35 U.S.C. §103 cannot be sustained. Claims 10-14 depend from Claim 9 and include all the limitations thereof, and are thus in condition for allowance.

Claim 15

Independent Claim 15 recites in part,

"(a) a dilution indicator source;

(b) a catheter connectible to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream sensor *a fixed distance from the indicator port* for producing a signal corresponding to passage of the dilution indicator external to the catheter; and

(c) a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor ...." [emphasis added]

Examiner Szmal has not provided a specific rejection of Claim 15. Therefore, prior deficiencies of the cited references apply. As the assembly described in Vogel requires and

employs a stenosis reducing member and dilution indicator port being longitudinally (axially) moveable relative to the sensor of the steerable guidewire, the above recited limitation is not present in Vogel and in fact is expressly contrary to Vogel.

Again, the relative positions of Vogel are contrary to the present claims.

Quinn is directed to flotation balloon catheter and is not directed to reducing stenosis of a vessel. Vogel employs a steerable guide wire which commit or blood flow, wherein the guide wire can be used in conjunction with a separate catheter. There is no particular finding why a continuous monitoring device is modified by a device that does not monitor and precludes continuous monitoring. The only basis for combining these references is applicant's disclosure. Therefore, the rejection of Claim 15 under 35 U.S.C. §103 cannot be sustained. As Claim 38 depends from Claim 15 and includes all the limitations thereof, Claim 38 is also in condition for allowance.

Claim 16

Independent Claim 16 recites a method including, in part:

"(a) inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the stenosis;

(b) introducing a first change in a blood property in a blood flow outside the catheter and a fixed distance from the blood property sensor and upstream of the blood property sensor;

(c) detecting passage of the first change in the blood property at the blood property sensor;

(d) reducing the stenosis in the vessel;

(e) introducing a second change in the blood property upstream of the sensor;

(f) detecting passage of the second change in the blood property at the blood property sensor; and

(g) determining a change in blood flow corresponding to (i) the detected passage of the first change in the blood property, (ii) the second change in the blood property...."

Examiner Szmal has not provided a specific rejection of Claim 16. Applicant assumes the following assertion by the Examiner is the basis for the rejection of Claim 16.

"Since both Quinn et al. and Vogel et al. disclose means for measuring the flow rate within a blood vessel by a dilution technique, it within obvious to an ordinary skill in the art at the time the invention is made to modify die and [sic] method of Quinn et al. to include the use of a specific blood flow formula, the use of multiple catheters and reducing a stenosis using the balloon, as per the teachings of Vogel et al., since it would provide a means to measure the pre- and post-angioplasty flow rates to determine if further balloon inflation is necessary to reduce the blockage." [23, Page 4]

The asserted reason for the combination is not based on either cited reference, but rather a reconstruction of the purpose of applicant's invention. The blood property sensor of Vogel is disposed on the steerable guidewire and the port for introducing a dilution indicator is through the terminal end of the separate and axially translatable dilatation catheter. Thus, there can be no introducing a first change in the blood property in the blood flow outside the catheter at a fixed distance from the blood property sensor.

The failure of the cited references to disclose the limitations of the claims as well as the lack of independent and particular reason to combine, precludes the rejection of Claim 16 under 35 U.S.C. §103 from being sustained. As Claims 17, 18, 39 and 40 depend from Claim 16 and include all limitations thereof. these claims are also in condition for allowance.

Claim 19

Independent Claim 19 recites "A method of monitoring blood flow during a vascular corrective procedure. comprising:

(a) inserting a catheter into a vessel;

(b) employing the catheter to perform a vascular correction in the vessel;

(c) introducing a first blood property change into a blood flow outside the catheter;

(d) detecting passage of the first blood property change past a downstream sensor on the catheter; and

(e) calculating the blood flow in response to the change in blood property and passage of the blood property past the downstream sensor...."

Primary reference Quinn fails to disclose steps a and b. The steerable guide wire of Vogel requires independent movement of the guide wire and an associated catheter. As Vogel employs a steerable guidewire to detect passage of a blood property change and the separate and

axially translatable dilatation catheter is used to perform the angioplasty, applicant respectfully submits Claim 19 is in condition for allowance.

Further, Examiner Szmal has merely asserted whichever "obvious" variation is required. That is, it is apparently obvious to use one and two catheters in view of the cited references. Therefore, the rejection of Claim 19 under 35 U.S.C. §103 cannot be sustained. As Claim 41 depends from Claim 19 and includes all the limitations thereof, this claim is also in condition for allowance.

Claim 22

Independent Claim 22 recites "An apparatus for determining an intra-procedural blood flow in a vascular corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter located to alter a blood parameter external to the catheter;

(c) means for effecting the corrective produce; and

(d) a blood parameter sensor connected to the catheter and spaced *a fixed distance* from the blood parameter altering section two sense the altered blood parameter external to the catheter and provide a signal for determining the blood flow ...." [emphasis added]

That is, the sensor and blood parameter altering section are spaced a fixed distance apart.

In contrast, the assembly of Vogel employs and requires sensors on a steerable guidewire which is axially translatable relative to the dilatation catheter having the indicator dilution port. The combination asserted by Examiner Szmal fails to account for the inherent distinctions between floatation balloons and stenosis reducing members. In addition, the Examiner has not provided any basis, absent the present disclosure, for the selective picking and choosing of certain limitations, without addressing the exclusion of expressly related structure. It would be contrary to Quinn to interrupt the continuous monitoring. Therefore, the rejection of Claim 22 under 35 U.S.C. §103 cannot be sustained. As Claims 23 and 24 depend from Independent Claim 22 and include all limitations thereof, these claims are also in condition for allowance.

Claim 25

Independent Claim 25 recites "A method of monitoring a stenosis reducing procedure in a vessel, comprising:

(a) locating a blood parameter altering section in the vessel to alter a blood parameter in a blood flow contacting the vessel;

(b) locating a blood parameter sensor *a fixed distance* downstream of the altering section;

(c) performing the stenosis reducing procedure; and

(d) determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor....." [emphasis added]

Examiner Szmal has not set forth a specific rejection of Claim 25. As Vogel requires a variable and adjustable distance between the steerable guidewire and the balloon of the dilatation catheter, this limitation is absent from the cited reference. Not only is this asserted combination not supported by the cited references, it impermissibly relies upon the present application and is therefore hindsight. Only by selectively picking and choosing from the references (and ignoring the stated purpose of each reference) is the examiner's combination possible. Quinn cannot perform stenosis reducing procedures, and to modify Quinn to prevent continuous monitoring is contrary to Quinn. Therefore, the rejection of Claim 25 under 35 U.S.C. §103 cannot be sustained.

As Claims 26, 27, 28 and 29 depend from Claim 25 and include all limitations thereof, these claims are also in condition for allowance.

Claim 35

Independent Claim 35 recites in part, "a catheter having means for increasing the effective size of a portion of the vascular passage . . . and a downstream blood property sensor affixed to the catheter."

As Vogel does not disclose or suggest a blood property sensor affixed to a catheter having a means for increasing the effective size of a portion of the vascular passage, and Quinn does not disclose means for increasing the effective size of a portion of the vascular passage, Claim 35 is in condition for allowance.

As Claims 37 depends from Claim 35 and includes all limitations thereof, this claim is also in condition for allowance.

Therefore, applicant respectfully submits all the pending claims, Claims 2-6, 9-19 and 22-42 are in condition for allowance and such action is earnestly solicited. If, however, Examiner Szmal feels that any further issues remain, he is cordially invited to call the undersigned so that such matters can be promptly resolved.

Respectfully submitted,

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